K102227

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Sponsor Information:
Atom Medical Corporation
3-18-15, Hongo, Bunkyo-ku
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Japan

JAN 2 1 2011

Date Summary Prepared: July 30, 2010

Contact Person:
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Device Name:
Trade Name(s): Infa Warmer *i* (Atom Infant Warmer Model 103)
Classification Name: Infant Radiant Warmer
Classification Regulation: 880.5130
Panel: General Hospital
Product Code: FMT

Predicate Device Information:
Device Name: V-505 Infa Warmer
510(k) Reference: K060461
Manufacturer: Atom Medical Corporation

Device Description:
Infa Warmer *i* (Atom Infant Warmer Model 103) consists of a canopy, a warming heater (heater), a pole, a control panel, a mattress, a mattress platform, baby guards and a stand with casters.
This product has 3 types (Type Name: HE, MS, ST) according to the following specification.
HE: (1)With mattress platform, stand can go up and down
MS: (2)With mattress platform, stand cannot go up and down
ST: (3)Without mattress platform
A warming heater is installed in the canopy.
Skin temperature sensors are connected to front panel of the pole.
This product has 2 types of function modes; one is "servo control model" (called as "skin temperature control mode") and another is manual control mode.
In "servo control mode", skin temperature can be set from 34°C to 38°C
In "manual control mode", heater output of the warming heater can be set from 0 to 100% (in 5% increments).
When the product is functioned in "servo control mode", baby's skin temperature is monitored by temperature sensor attached on baby's body, and baby's skin temperature is controlled according to difference between monitored baby's skin temperature and set skin temperature.

When the product is functioned in "manual control mode", heater output of the warming heater is controlled manually according to measured baby's skin temperature.
The mattress platform can be tilted.
The skin temperature sensors and X-ray cassette tray are accessories.
The X-ray cassette tray is optional accessory, and it can be installed under the mattress platform.
These accessories are available separately as replacements.

SpO2 module is component of this product, and it is optional whether they are attached initially or not. If it is not attached initially, it can be attached later, and SpO2/pulse monitoring can be available. The component can be supplied individually.

This product has a space inside the pole, and gas powered resuscitator or oxygen/air gas blender whose sizes are within the space, can be installed in the space, so that resuscitation or oxygen therapy can be done immediately for any new born baby who needs such the treatments. When the resuscitator or the blender is installed in this space, it is completely separated from this product, and it does not have any connections with this product regarding function, operation and power source. Therefore, this product operates normally without the resuscitator or the blender. Also, this product operates normally, even if the resuscitator or the blender is out of order.

Intended Use:
The Infa Warmer *i* is a radiant-warming open-type incubator for newborns and premature neonates. It is intended for pre-operative and post-operative intensive care in neonatal surgery, temperature control in neonatal hypothermia, observation and examination in newborn nurseries, prevention of body temperature drop shortly after delivery, etc. The Infa Warmer *i* is provided with the temperature control function to control the infant's skin temperature and optional functions include pulse oximetry and oxygen density controlling.

Comparison to Predicate Device:
Main differences between Infa Warmer *i* and Atom V-505 are as follows.

The functions of oxygen delivery and suction are installed in Atom V-505 but are not installed in the Infa Warmer *i*.

The technological characteristics of the Infa Warmer *i* as compared to the predicate products, the V-505 Infa Warmer, is equivalent in the following areas and do not compromise the safety or efficacy of the device.

- -Intended use
- - Feature
- - Appearance
- - Temperature Modes
- - Components and those function

Testing and Conclusions:
Infa Warmer *i* is electrical medical device. Therefore, tests based on IEC60601-1, IEC60601-1-2 and IEC60601-2-21 standards were carried out for Infa Warmer *i*, and it was verified that Infa Warmer *i* is met to requirements of IEC60601-1, IEC60601-1-2 and IEC60601-2-21.

Biocompatibility was evaluated based on ISO10993-1. Infants-contacting parts of the Infa Warmer *i* are not unprecedented and are generally used for various type of medical devices. And

also, the materials are identical to those used for the 510(k)-cleared predicate device. Thus the biological safety can be evaluated to have been assured.

Validation has been conducted on the device software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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JAPAN

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Re: K102227
Trade/Device Name: Infa Warmer *i* (Atom Infant Warmer Model 103)
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: II
Product Code: FMT
Dated: January 17, 2011
Received: January 18, 2011

Dear Mr. Sugino:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

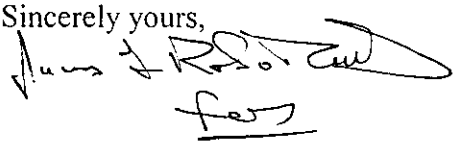
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Infa Warmer *i* (Atom Infant Warmer Model 103)

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Prescription Use ___XX____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Richard Chapman

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K022277